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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/786,937	01/22/1997	PHILIPPE BOUCHARD	235299/96001	5859

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/786,937	BOUCHARD ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-128* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 1997* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/10/03;8/3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to the request for continued examination and amendment received Aug. 3, 2004.

Claims 1-37 are cancelled. New claims 38-128 are added. Claims 38-128 are currently pending.

All previous claim rejections maintained in the final rejection mailed Nov. 3, 2003 are withdrawn in view of the following new ground(s) of rejection. Applicant's arguments concerning these rejections have been considered but are moot in view of the following new ground(s) of rejection.

Applicant's Information Disclosure Statements received Oct. 10, 2003 and Aug. 3, 2004 have been considered. Please refer to Applicant's copies of the 1449s submitted herewith.

Specification

The specification is objected to because it does not contain a section entitled "BRIEF DESCRIPTION OF THE DRAWINGS". Appropriate correction is requested.

New Ground(s) of Rejection

Claim Objection(s)

1. Claims 87-88, 95-96, 103-104, 111-112 are objected to because of the following informalities: in claims 87-88, 95-96, 103-104 and 111-112, line 1, "for from" renders the claim awkward and should be reworded. Appropriate correction is required.

Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 53-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites the limitation "LHRH antagonist" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 54 recites the limitation "LHRH antagonist" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 55 recites the limitation "the LHRH antagonist" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 56 recites the limitation "the LHRH antagonist" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejection(s)—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 38-39, 41-43, 46, 47, 48, 49, 50, 51, 52, 54-55, 58, 59, 60, 61-62, 64-66, 69-70, 71, 72-74, 76-77, 80-81, 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Olivennes et al.

Olivennes et al. disclose the invention substantially as claimed. Specifically, Olivennes et al. teach a method of carrying out controlled ovarian hyperstimulation in 17 women, wherein an amount of the exogenous gonadotropin hMG is administered to the women starting on day 2 of the menstrual cycle. Then a dose of 5 mg of Cetrorelix, an LHRH antagonist, is administered subcutaneously. A second injection was performed 48 hours later if the triggering of ovulation was not decided in the meantime. Six patients received one injection and 11 patients received two administrations. Plasma LH levels showed a marked decrease and remained low after the administration of Cetrorelix. Ovulation was triggered by administering an effective amount of the hormone hCG. The end result of the study was that six clinical pregnancies were obtained. Olivennes et al. disclose that the LHRH antagonist, Cetrorelix, in a single or dual administration protocol was able to prevent LH surge in all of the 17 patients studied. Please see the abstract; page 469, "Study Protocol"; page 475, last full paragraph.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 40, 44, 45, 53, 56-57, 63, 67-68, 75, 78-79, 83-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olivennes et al., supra in view of Reissmann et al.

Olivennes et al. as applied above.

Olivennes et al. do not disclose administering 3 mg of Cetrorelix or administering Cetrorelix starting cycle day 4-8 or 6-10. However, the Examiner refers to Reissmann et al., which disclose a study in which patients were stimulated with HMG. Then starting on cycle day 7, cetrorelix was administered subcutaneously to the patients. Three hours before inducing ovulation, LH measurements showed a decrease in LH levels. Please see page 1978, first column, third full paragraph.

Additionally, Reismann et al. disclose another study where patients, involved in assisted reproduction techniques, were successfully stimulated after pretreatment with

Cetrorelix by daily administration starting on cycle day 7 until induction of ovulation. The fertilization rate was 61.5% and the mean amount of HMG needed was only 27 ampoules versus 40-50 ampoules in another study. Please also see page 1978, second column, second full paragraph.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of Olivennes et al. by administering 3 mg of Cetrorelix starting on cycle day 7 because, based on the desirable results disclosed in Reismann et al., one of ordinary skill in the art would reasonably expect such a lower dosage and administration starting point to prevent premature LH surges thereby producing fertilizable oocytes.

Concerning the claimed dosage amount of 0.25 mg/day per multiple days, since Reismann et al. establish a correlation between the amount of cetrorelix administered and resulting plasma LH levels (please see again, page 1978, third full paragraph), it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the amount of Cetrorelix administered such that desired prevention of premature LH surges is achieved and maintained until ovulation is stimulated for assisted reproduction techniques.

With respect to claim 115, which does not require the administration of an exogenous gonadotropin, i.e. hMG, Reismann et al. disclose that premature LH surges in assisted reproduction technology (ART) can be prevented by short term applications of an LHRH antagonist, i.e. Cetrorelix, associated with a "reduced HMG requirement for ovarian stimulation" (please see the abstract). Therefore, it would have been obvious to

one of ordinary skill in the art at the time the invention was made to further modify the method of Olivennes et al. and Reismann et al. to omit the administration of HMG because one of ordinary skill in the art would reasonably expect the administration of cetrorelix to achieve prevention of unwanted premature LH surges while allowing for normal follicular growth the occur.

Concerning the claimed daily dosages, i.e 3 to 14 days, 3-7 days, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the daily dosages in the prior art such that unwanted LH surges are prevented thereby allowing for follicular growth to occur.

In addressing claims 124-125, 127-128, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of the prior art by substituting Cetrorelix with other conventional LHRH antagonists with the reasonable expectation that these other antagonists would be equally effective in preventing premature LH surges. Finally, extracorporeal fertilization by sperm injection as well as in vitro fertilization is conventional means of producing fertilizable oocytes and it would have been obvious and well with the capability of the skilled artisan to use them in the method of the prior art.

Conclusion

Hence, claims 38-128 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number

is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Dec. 12, 2004

Cybille Delacroix-Muirheid
Patent Examiner Group 1600